IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

JERRY LANE BIRDSONG and, BETTY BIRDSONG,	)	
Plaintiffs,	)	**Civil Action No: 3:10-01182**
	)	**Judge Campbell**
v.	)	**Magistrate Judge Knowles**
ELI LILLY AND COMPANY and, AMYLIN PHARMACEUTICALS, INC.,	)	**JURY DEMAND**
Defendants.	)	

DEFENDANT ELI LILLY AND COMPANY'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

Defendant Eli Lilly and Company ("Lilly"), pursuant to Federal Rule of Civil Procedure 12(b)(6), hereby submits its memorandum of law in support of its motion to dismiss the Sixth, Seventh, and Eighth Claims of Plaintiffs Jerry Lane Birdsong and Betty Birdsong's Second Amended Complaint for failure to state a claim upon which relief can be granted.

Lilly previously moved to dismiss Plaintiffs' original Complaint, which was filed on December 14, 2010 and sought recovery for injuries that Mr. Birdsong allegedly suffered as a result of ingesting Byetta®, a medicine manufactured and sold by Lilly and Amylin Pharmaceuticals, Inc. ("Amylin") (collectively "Defendants" or the "Companies"). Before the Court ruled upon that motion, Plaintiffs filed their first Amended Complaint and, soon after, sought leave to, and ultimately did, file their Second Amended Complaint (referred to herein as "Amended Complaint"),[1] alleging additional facts and two additional claims.

[1] Plaintiffs filed their first Amended Complaint on January 18, 2001 (Docket Entry No. 14), and moved to amend and/or correct this pleading just over one week later (Docket Entry No. 20). The Court granted this motion on February 8, 2011 (Docket Entry No. 33) and Plaintiffs' Second Amended Complaint was docketed that same day (Docket Entry No. 34).

Plaintiffs' Amended Complaint is inadequately pled and fails to allege facts sufficient to support their vicarious liability and Tennessee Consumer Protection Act (hereinafter "TCPA") claims. Plaintiffs seek to impose vicarious liability between Lilly and Mr. Birdsong's prescribing physician based on theories of joint venture/joint enterprise and concerted activity. But Defendants are left with little more than their best guess as to what facts Plaintiffs contend support these claims. Plaintiffs' vicarious liability theories are unsupported, inconsistent, and cannot be reconciled with other allegations set forth in their Amended Complaint.

Plaintiffs also fail to allege facts sufficient to support their claim under the TCPA. Indeed, Plaintiffs' Amended Complaint not only fails to allege facts sufficient to state a claim under the TCPA, but it also affirmatively demonstrates Plaintiffs' inability to recover under the statute.

For the reasons discussed in further detail below, Claims Six, Seven, and Eight should be dismissed.

I. MOTION TO DISMISS STANDARD

Plaintiffs' TCPA claim and vicarious liability theories are not supported by facts demonstrating a plausible right to relief and, thus, cannot advance beyond the pleading stage. "[A] plaintiff armed with nothing more than conclusions" cannot "unlock the doors of discovery," as "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Dismissal of claims is appropriate under Rule 12(b)(6) when the pleadings fail to allege facts "sufficient to raise a right to relief above the speculative level" and fail to "state a claim to relief that is plausible on its face." *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (internal quotations omitted). Plaintiffs' Amended

Complaint must allege "more than labels and conclusions, and a formulaic recitation of a cause of action's elements" is not sufficient to survive a motion made pursuant to Rule 12(b)(6). *Twombly*, 550 U.S. at 555. Because it fails to do so with respect to its TCPA and vicarious liability claims, these claims must be dismissed.

II. FACTUAL BACKGROUND

A. Plaintiffs Allege That Mr. Birdsong Received Free Samples of Byetta® and a Patient Education Kit Before Suffering an Episode of Acute Pancreatitis.

Plaintiff Jerry Birdsong alleges that, on December 30, 2009, he suffered acute pancreatitis as the result of ingesting Byetta®, an injectable prescription medicine that may improve blood sugar control in adults with type 2 diabetes mellitus. *See* Am. Compl. ¶¶ 1, 10. Plaintiffs contend that on December 1, 2009, Dr. Michael Carlson prescribed Byetta® to Mr. Birdsong and provided him free samples and a patient education kit. *Id*. ¶¶ 7, 19, 105. Plaintiffs do not allege that they ever filled or paid for a Byetta® prescription. *Id*. ¶ 7. Plaintiff further claims that he now suffers from chronic pancreatitis. *Id*.

B. As Plaintiffs Recognize, Byetta®'s Label and Two FDA Alerts Warned of Acute Pancreatitis Prior to Mr. Birdsong's December 2009 Prescription.

More than three years before Dr. Carlson prescribed Byetta® to Mr. Birdsong, the label accompanying the medicine warned doctors and consumers of acute pancreatitis. As Plaintiffs recognize, on various occasions after Byetta®'s approval in April 2005, the Companies revised the label to include "warnings concerning the risk of pancreatitis." *Id*. ¶ 15. In addition, on two separate occasions, FDA issued communications concerning pancreatitis and use of Byetta®.

On October 12, 2006, the Companies revised the Byetta® label to include a warning about several adverse reactions — including acute pancreatitis — observed in patients taking Byetta®. Byetta Package Insert, Oct. 12, 2006, at 15 (attached hereto as Exhibit A).[2]

On October 16, 2007, FDA issued an alert to healthcare professionals stating that FDA had reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta and that an "association between Byetta® and acute pancreatitis" was suspected in some of those cases. FDA Alert, Information for Healthcare Professionals: Exenatide (marketed as Byetta) – 10/2007, Oct. 16, 2007 (attached hereto as Exhibit B) (cited in Am. Compl. ¶ 22).

Also in October 2007, the Companies revised the Byetta® label to include a paragraph-long warning about acute pancreatitis under the heading "**PRECAUTIONS**":

> Postmarketing cases of acute pancreatitis have been reported in patients treated with BYETTA. Patients should be informed that persistent severe abdominal pain, which may be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. If pancreatitis is suspected, BYETTA and other potentially suspect drugs should be discontinued, confirmatory tests performed and appropriate treatment initiated. Resuming treatment with BYETTA is not recommended if pancreatitis is confirmed and an alternative etiology for the pancreatitis has not been identified.

Byetta Package Insert, Jan. 11, 2008, at 11 (attached hereto as Exhibit C) (cited in Am. Compl. ¶22). Byetta's January 1, 2008 label also included a section entitled "Information for Patients" that instructed physicians as follows: "Patients should be informed that persistent severe abdominal pain, which may be accompanied by vomiting, is the hallmark symptom of acute

[2] The Amended Complaint refers to the Byetta prescribing information and FDA Alerts, but fails to cite to the full labeling or Alerts that address acute pancreatitis, or attach the referenced documents. *See, e.g.*, Am. Compl. ¶¶ 22, 23. Lilly is attaching the referenced FDA-approved labeling, FDA Alerts, and FDA correspondence as Exhibits A through E, and requests this Court take judicial notice of them. Consideration of these documents, which are published on FDA's website, referenced in the Amended Complaint, and subject to judicial notice, will not convert this motion to dismiss into a motion for summary judgment. *See, e.g.*, *Shearer v. Adams*, No. 09-991, 2010 U.S. Dist. Lexis 100315, at *16 (M.D. Tenn. Sept. 21, 2010); *Autozone v. Glidden Co.*, No. 08-2851, 2010 U.S. Dist. Lexis 94699, at *9 (W.D. Tenn. Sept. 10, 2010) (When ruling on a Rule 12(b)(6) motion "[t]he Court may also consider 'documents incorporated into the complaint by reference, and matters of judicial notice.'") (quoting *Tellabs, Inc., v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)).

pancreatitis and be instructed to contact their physician if this symptom occurs (see PRECAUTIONS)." *Id*. at 13.

On August 18, 2008, FDA issued an updated alert to healthcare professionals regarding Byetta®, discussing that it had received reports of patients taking Byetta® and developing hemorrhagic or necrotizing pancreatitis. FDA Alert, Information for Healthcare Professionals: Exenatide (marketed as Byetta) – 8/2008 Update, Aug. 18, 2008 (attached hereto as Exhibit D) (cited in Am. Compl. ¶ 23).

In October 2009, the Companies revised the Byetta® label to advise patients that based on postmarketing data, Byetta® has been associated with acute pancreatitis under the heading "**WARNINGS AND PRECAUTIONS**." *See* Byetta Full Prescribing Information, Oct. 30, 2009, at 3 (attached hereto as Exhibit E) (referenced in Am. Compl. ¶¶ 16-17). At that time, in a letter to Defendant Amylin, FDA required a Medication Guide, pursuant to 21 CFR Part 208, to make patients aware of the "serious risks" of Byetta and to ensure "patients' safe and effective use" of the medicine. Am. Compl. ¶ 18. The FDA also approved Amylin's communication plan for communicating these changes, which included a letter to all healthcare providers who prescribed Byetta® within the proceeding 12 months. *See* FDA October 30, 2009 Letter to Amylin (attached hereto as Exhibit F) (cited in Am. Compl. ¶ 18).

C. Plaintiffs Allege That Mr. Birdsong Received Outdated Warnings from His Physician.

Plaintiffs do not contend that Dr. Carlson was unaware of the above warnings or that those warnings were inadequate.[3] They recognize that many of the revisions to the Byetta®

[3] In fact, before this Court, Plaintiffs have recognized that the October 2009 warnings regarding pancreatitis are adequate. *See* Pls.' Opp'n to Mot. to Dismiss, at 9 (filed Jan. 20, 2011) (contending that Dr. Carlson received "inadequate warnings concerning Byetta®," absent evidence he "read, received, or was aware" of the October 2009 warnings).

label since its approval in April 2005, as well as FDA communications, contained warnings concerning the risk of pancreatitis. *See* Am. Compl. ¶¶ 15, 23-24. Instead, the crux of Plaintiffs' Amended Complaint is that, in December 2009, Dr. Carlson gave Mr. Birdsong free samples and a patient education kit that did not contain the most recent, i.e., October 2009, label revisions. *See id*. ¶¶ 19, 115, 122. Plaintiffs claim that "nothing in the patient education kit [] included any mention of any potential side effect of pancreatitis or acute pancreatitis," *id*. ¶ 71, and "that defective and inadequate warnings were given to Plaintiff's physician in that the free samples and kit contained no warnings of the risk of pancreatitis or kidney damage," *id*. at 74.

D. Plaintiffs Mischaracterize Dr. Carlson's Participation in the Healthcare Professional Education Programs.

While Plaintiffs correctly state that Dr. Carlson participated in Lilly's Healthcare Professional Education Programs, they inaccurately describe this activity by quoting the explanation of Lilly's Patient Education Programs found on its web site. *See* Am. Compl. ¶ 107 (alleging ". . . as part of Lilly's ***Healthcare Professional Educational Programs*** which Lilly describes on its website as follows: ***Patient Education Programs*** . . .") (emphasis added).

Immediately following the paragraph of Lilly's web site that is inaccurately quoted in the Amended Complaint is a description of the program in which Dr. Carlson actually participates—Lilly's Healthcare Professional Education Programs:

> **Healthcare Professional Education Programs**
> Healthcare Professional Education Programs are speaker programs intended to enhance the knowledge and patient care expertise of healthcare professionals. Led by contracted healthcare professionals, these programs feature education on:
>
> Data from clinical trials on the effectiveness and safety of Lilly medicines
> Application of data in clinical practice
> Medication dosage, frequency of administration, and duration of use
> Information about the underlying disease, disease management, and epidemiology

> Symptom identification, patient presentation, and diagnosis
> Speaker presentations and educational materials are developed by Lilly professionals in collaboration with contracted expert advisors, many of whom are respected academics. All programs must adhere to U.S. Food and Drug Administration regulations.

Lilly Faculty Registry, About Lilly Faculty, http://www.lillyfacultyregistry.com/pages/about-lilly-faculty.aspx (last visited Feb. 14, 2011) (cited in Am. Compl. ¶ 107 & n.5). Thus, Dr. Carlson participated in "speaker programs intended to enhance the knowledge and patient care expertise of healthcare professionals." *Id*. Plaintiffs' allegations that Lilly paid Dr. Carlson "to help inform patients" and assist Lilly in fulfilling its "FDA mandated duty to inform patients" are simply not true and contradicted by the very source Plaintiffs cite.[4] *See* Am. Compl. ¶¶ 106-10, 112-13, 119.

III. ARGUMENT

Claims Six, Seven, and Eight of Plaintiffs' Amended Complaint must be dismissed pursuant to Rule 12(b)(6). Plaintiffs' joint enterprise/joint venture and concerted action theories are supported by little more than a bare recitation of the elements of these claims. The "facts" that they allege in their attempt to concoct a common purpose or concerted activity are unclear, inaccurate, and inconsistent with other allegations in the Amended Complaint. Moreover, Plaintiffs also fail to allege facts sufficient to establish that they are entitled to relief under the TCPA, because the injuries for which they seek to recover are outside the scope of the statute.

[4] Lilly is not suggesting that it does not assist Dr. Carlson in providing information he could use, at his discretion, with patients. Rather, Lilly does contend that Plaintiffs' allegations that it paid Dr. Carlson to inform patients of relevant information is inaccurate and not supported by the facts alleged and sources cited in the Amended Complaint.

A. Plaintiffs' Factual Allegations Are Insufficient to Establish a Joint Enterprise/Joint Venture.

Plaintiffs fail to allege facts sufficient to establish their joint enterprise/joint venture claim. Courts applying Tennessee law have identified four elements relevant to determining whether a joint venture exists and the negligence of one of the parties may be imputed to the other: (1) a common purpose, (2) an agreement, express or implied, (3) an equal right on the part of each to control both the venture as a whole and any relevant instrumentality, and (4) the intent of the parties to share the profits from their joint enterprise. *See Fain v. O'Connell*, 909 S.W.2d 790, 792-93 (Tenn. 1995); *Cecil v. Hardin*, 575 S.W.2d 268, 271-72 (Tenn. 1978); *Spencer Kellogg & Sons, Inc. v. Lobban*, 315 S.W.2d 514, 520 (Tenn. 1958); *Schwartz v. Johnson*, 280 S.W. 32, 33 (Tenn. 1926); *Messer Griesheim Indus., Inc. v. Cryotech, Inc.*, 131 S.W.3d 457, 469-70 (Tenn. Ct. App. 2003); *Bryant v. McCord*, No. 01A01-9801-CV-00046, 1999 Tenn. App. LEXIS 26, at *11 (Tenn. Ct. App. Jan. 12, 1999). While "no one fact or circumstance may be pointed to as a conclusive test" that a joint enterprise exists, *Messer*, 131 S.W.3d at 469-70, the Tennessee Supreme Court has reasoned that "common interest [/] purpose and equal right of control are essential components of a joint venture," *Fain*, 909 S.W.2d at 793.

Here, Plaintiffs fail to allege facts sufficient to establish the "essential components of a joint venture." They also fail to establish that Dr. Carlson and the Companies intended to share the profits from their alleged joint enterprise.

1. Plaintiffs Fail to Accurately Allege a Common Purpose That Encompasses the Alleged Wrongful Conduct.

Plaintiffs allege that a joint enterprise between Dr. Carlson and Lilly was established for the common purpose of informing patients of the risks associated with the use of Byetta®. *See* Am. Compl. ¶¶109, 112. This theory is untenable, however, because it is based upon a mischaracterization of the very authority cited by Plaintiffs in their Amended Complaint. While

Dr. Carlson has participated in Lilly's Healthcare Professional Education Programs, this program is designed to educate healthcare professionals on topics such as clinical trial data or disease management. *See supra* Part II.D.[5] Contrary to Plaintiffs' assertions, Lilly did not pay Dr. Carlson "to help inform patients." *See* Am. Compl. ¶ 108-09.

Plaintiffs' allegation that "Defendants and Plaintiff's treating physician shared a common purpose to prescribe and dispense Byetta and more specifically to inform patients concerning risks of Byetta" is inaccurate and irrelevant. *Id.* ¶ 112. Unlike Dr. Carlson, the Companies do not prescribe or dispense Byetta® to patients. Moreover, that the Companies and Dr. Carlson both seek to inform patients of any risks associated with Byetta® is irrelevant and insufficient to establish a joint enterprise and justify the imposition of vicarious liability. Plaintiffs, therefore, have failed to allege facts sufficient to establish this essential component of a joint enterprise.

2. Plaintiffs Fail to Allege an Equal Right to Control the Alleged Venture and Relevant Instrumentality.

Plaintiffs allege that "Defendants and Plaintiffs' [sic] treating physician each had an equal right 'to control both the venture as a whole and any relevant instrumentality.' Specifically, the Byetta warnings, box and kit were jointly supplied, dispensed and controlled by Defendants and Dr. Carlson." Am. Compl. ¶114. This allegation contains nothing "more than labels and conclusions, and a formulaic recitation of a cause of action's elements." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). It is also inconsistent with Plaintiffs' other factual allegations. For example, as Plaintiffs recognize in their Amended Complaint, the Companies,

[5] As explained more fully in the subsequent sections, Dr. Carlson's participation in the Healthcare Professional Education Programs is insufficient to establish a joint enterprise. Even assuming *arguendo* that this participation were sufficient, Plaintiffs' allegations would still be lacking, because, at best, they would seek to impute liability for alleged wrongful conduct (failure to warn) that falls outside the scope of the alleged enterprise (educating healthcare professionals). Each party to a joint venture can only subject other members "to liability to third persons in matters which are strictly within the scope of the joint enterprise." *Robertson v. Lyons*, 553 S.W.2d 754, 757 (Tenn. Ct. App. 1977); *see also Golec v. A-1 Ditching Co.*, No. 1365, 1990 Tenn. App. LEXIS 900, at *3 (Tenn. Ct. App. Dec. 21, 1990) (same).

working with FDA, are responsible for the content and format of Byetta®'s label and packaging. *See, e.g., id*. ¶¶ 5-6, 17-18, 50. Dr. Carlson has no right to control the content of Byetta®'s label. As Plaintiffs also appear to recognize, Dr. Carlson alone has the authority to prescribe or to provide a free sample of Byetta® to one of his patients. *See, e.g., id*. ¶¶ 64-65, 76-77. The Companies cannot usurp Dr. Carlson's prescribing decisions or dictate the information that he provides to his patients. Plaintiffs simply do not adequately plead an equal right to control the alleged venture and relevant instrumentality.

3. Plaintiffs Fail to Allege That Dr. Carlson and the Companies Intended to Share the Profits of the Alleged Joint Venture.

Nothing in Plaintiffs' Amended Complaint even suggests that Dr. Carlson and the Companies intended to share the profits of their alleged joint venture. While Plaintiffs do allege that Dr. Carlson received payment for his participation in the Healthcare Professional Education Programs, the fact that each may have expected to benefit from the arrangement does not mean that they expected to share profits. *See Grieshem v. Cryotech, Inc.*, 45 S.W.3d 588, 607 (Tenn. Ct. App. 2001) (finding no evidence of a joint venture and reasoning that "[t]he fact that each of the defendants expected to profit from the relationships does not mean that they expected to share the profits of [one defendant's] business"). Rather, the circumstances must show that the parties intended to share the profits from their joint enterprise. *Messer*, 131 S.W.3d at 470, 472 (emphasizing that it is profits—the net amount after deduction of proper expenses incident to the business—that must be subject to sharing).

Here, there simply are no factual allegations in the Amended Complaint demonstrating an intention or understanding to share profits.

B. Plaintiffs' Factual Allegations Are Insufficient to Establish That Dr. Carlson and Defendants Acted in Concert.

Plaintiffs fail to allege any facts to support their bald, legal conclusions that Dr. Carlson and Defendants "acted tortiously in concert with each other pursuant to a common plan" and "gave substantial assistance to the other." *See* Am. Compl. ¶ 119-121. Their allegations are essentially a recitation of the elements of a concert of action theory set forth in the Restatement (Second) of Torts, and fail to identify the facts that serve as the basis for their claim.

This theory of liability applies when two or more persons engage in an unlawful act and one of them commits a civil injury upon a third person, in which case all are equally liable. *Huckeby v. Spangler,* 521 S.W.2d 568, 573 (Tenn. 1975). "A person is deemed to act in concert when he acts with another to bring about some preconceived result." *Smith v. Methodist Hospitals*, 995 S.W.2d 584, 589 (Tenn. Ct. App. 1999). Thus, one can be held liable for harm to a third party as a result of another's tortious conduct if he

> (a) does a tortious act with the other or pursuant to a common design with him, or
>
> (b) knows that the other's conduct constitutes a breach of duty and gave substantial assistance or encouragement to the other so as to conduct himself, or
>
> (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered constitutes a breach of duty to third persons.

Bryant, 1999 Tenn. App. LEXIS 26, at *34-35 (quoting Restatement (Second) of Torts §876(c)).

In *Bryant*, the court rejected plaintiff's contention that the defendant hospital, CMC, was vicariously liable for the medical malpractice of the defendant orthopedic surgeon who performed back surgery on the plaintiff at CMC. *Id*. at *31-35. Asserting a concerted action theory, the plaintiff claimed that by failing to supervise the doctor and allowing him to use its

facilities, the hospital substantially assisted the doctor in breaching his duty of care. *Id*. at 35. The court found that even if those facts were true, they would not constitute substantial assistance on the part of the hospital. *Id.*

Here, Plaintiffs' allegations are even less specific than those rejected in *Bryant*. The Amended Complaint is entirely unclear as to what "preconceived result" the Companies and Dr. Carlson sought to achieve, or what substantial assistance or encouragement one provided to the other.[6] To support their concerted activity theory, Plaintiffs likely must allege that the Companies and Dr. Carlson sought to conceal the warnings of pancreatitis and the use of Byetta® from patients. Plaintiffs fail to plead as such. But even if they did make such an allegation, it could not be reconciled with their contention that Defendants failed to warn Dr. Carlson of the risks of pancreatitis. *See* Am. Compl. ¶¶ 57, 74, 84.

C. Plaintiffs' Personal Injury Claims Do Not Fall Within the Scope of the Tennessee Consumer Protection Act of 1977, Tenn. Code. Ann. § 47-18-101 *et seq*.

Plaintiffs' failure to allege an ascertainable loss of money or property dooms their TCPA claim. The TCPA allows a private right of action for damages when a person "suffers an ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value" as a result of an unfair or deceptive act of another. Tenn. Code. Ann. § 47-18-109(a)(1). Courts interpreting the TCPA have held that claims for personal injury or wrongful death are outside its scope. *Kirksey v. Overton Pub, Inc.*, 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990) (dismissing TCPA claim and holding "that the General Assembly intended for the Consumer Protection Act to be used by a person claiming damages for an ascertainable loss

[6] To the extent Plaintiffs' theory rests on the notion that Dr. Carlson and Defendants entered into a formal arrangement to "inform patients" of the risks associated with the use of Byetta®, it must be rejected for the reasons explained *supra* in Part III.A.1.

of money or property . . . not in a wrongful death action"); *Howard v. R.J. Reynolds Tobacco Co.*, No. 05-27, 2005 U.S. Dist. Lexis 34458, at *9 (E.D. Tenn. Aug. 25, 2005). *Accord* Tenn. Prod. Liab. Act, Tenn. Code Ann. § 29-28-102(6) (defining product liability action to "include[] all actions brought for or on account of personal injury, death or property damage caused by or resulting from the . . . labeling of any product").

In *Howard*, the court was faced with a *pro se* complaint and it was unclear whether the plaintiff asserted a separate personal injury claim against the defendant tobacco company, RJR. Recognizing the *Kirksey* court's limitation of compensable injuries under the TCPA, the court held that "to the extent [plaintiff] seeks to recover for injuries to his person resulting from [defendant's] alleged violations of the TCPA," those claims must be dismissed. *Id*. at *7-9. The court also held, however, that this does not "preclude Plaintiff from asserting a cause of action under the TCPA based upon non-personal injuries resulting from RJR's alleged unfair or deceptive acts nor does it preclude Plaintiff from asserting an independent personal injury cause of action." *Id*. at *9. Because plaintiff did not discuss "his alleged medical injuries" in the claim referencing the TCPA, the court construed the *pro se* pleading as asserting separate TCPA and personal injury claims. *Id*. at *9-10.

Unlike *Howard*, here, Plaintiffs discuss Mr. Birdsong's "alleged medical injuries" in the context of their TCPA claim. *See* Am. Compl. ¶ 102. Plaintiffs seek to recover for injuries that Mr. Birdsong allegedly sustained "to his person." *See id*. ¶ 8 ("This is an action to recover damages for personal injuries sustained by Jerry Birdsong. . . ."). Plaintiffs have not alleged "an ascertainable loss of money or property" that exists independently of those personal injuries. In fact, because Plaintiff received free samples of Byetta®, and the Amended Complaint does not allege that Plaintiffs ever paid for Byetta®, Plaintiffs are likely precluded from ever establishing

that they suffered "an ascertainable loss of money or property." *See* Am. Compl. ¶ 105. Because Plaintiffs' Amended Complaint does not set forth facts sufficient to establish a violation of the TCPA, Claim Six must be dismissed pursuant to Rule 12(b)(6).

IV. CONCLUSION

For the reasons set forth above, Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted with respect to Claim Six (Violation of the Tennessee Consumer Protection Act), Claim Seven (Joint Venture/Joint Enterprise), and Claim Eight (Acting in Concert). Lilly respectfully requests, therefore, that the Court dismiss these claims and provide all other relief it deems appropriate.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2011, a copy of the foregoing was filed electronically with the Clerk's office by using the CM/ECF system and served electronically or by U.S. mail upon the parties as indicated below. Parties may also access this filing through the Court's ECF system.

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